K123321

FEB 15 2013

510k Summary

Dimension® Chemistry III Calibrator (CHEM III CAL)

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. 510(k) Number

2. Applicant: Rose T. Marinelli
Siemens Healthcare Diagnostics, Inc.
P.O. Box 6101, Newark, DE 19714-6101
Office Number: 302-631-8805; Fax Number: 302-631-6299

3. Date: October 25, 2012

4. Proprietary and Established Names:

Dimension® Chemistry III Calibrator (CHEM III CAL)

5. Regulatory Information:

Chemistry III Calibrator (CHEM III CAL)

Regulation section: 21 CFR 862.1150 Calibrator, Multi-Analyte
Classification: Class II
Product Code: JIX
Panel: Clinical Chemistry

6. Predicate Devices:

The predicate device used to demonstrate substantial equivalence to the Dimension® Chemistry III Calibrator (CHEM III CAL) is the Dimension Vista® Chemistry 3 Calibrator (CHEM 3 CAL) previously cleared under k062334.

7. Device Description:

The Chemistry III Calibrator (CHEM III CAL) is a three level, liquid calibrator. It is packaged as a kit of six vials, two vials each of Levels 1, 2 and 3 with 2.5 mL per vial. CHEM III CAL is a multi-analyte, aqueous product containing ammonium bicarbonate, sodium carbonate and ethyl alcohol.

8. Intended Use:

The CHEM III CAL is an *in vitro* diagnostic product for the calibration of Ammonia (AMM), Carbon Dioxide (ECO2) and Ethyl Alcohol (ETOH) assays on the Dimension® clinical chemistry system.

9. Indication(s) for Use:

The CHEM III CAL is an *in vitro* diagnostic product for the calibration of Ammonia (AMM), Carbon Dioxide (ECO2) and Ethyl Alcohol (ETOH) assays on the Dimension® clinical chemistry system.

10. Substantial Equivalence Information:

Similarities for Dimension® CHEM III CAL

Feature	New Device: Dimension® Chemistry III Calibrator (CHEM III CAL) (DC130)	Predicate: Dimension Vista® Chem 3 Calibrator (CHEM 3 CAL) (KC130) k062334
Preparation	Liquid: Provided ready to use.	Liquid: Provided ready to use.
Storage	2 – 8 °C	2 – 8 °C
Matrix	Aqueous product containing ethyl alcohol, ammonium bicarbonate and sodium carbonate.	Aqueous product containing ethyl alcohol, ammonium bicarbonate and sodium carbonate.
Traceability	AMM – ASC Grade Ammonium Sulfate EC02 – NIST SRM 351 ETOH – USP Grade Ethyl Alcohol	AMM – ASC Grade Ammonium Sulfate EC02 – NIST SRM 351 ETOH – USP Grade Ethyl Alcohol

Differences for Dimension® CHEM III CAL

Feature	New Device: Dimension® Chemistry III Calibrator (CHEM 3 CAL) (DC130)	Predicate: Dimension Vista® Chem 3 Calibrator (CHEM 3 CAL) (KC130)
Intended Use	The CHEM III CAL is an *in vitro* diagnostic product for the calibration of Ammonia (AMM), Carbon Dioxide (EC02) and Ethyl Alcohol (ETOH) assays on the Dimension® clinical chemistry system.	The CHEM 3 CAL is an *in vitro* diagnostic product for the calibration of Ammonia (AMON), Carbon Dioxide (C02) and Ethyl Alcohol (ETOH) methods on the Dimension Vista® System.
Units	µg/dL and µmol/L	µmol/L
Calibrator Levels	3 levels	2 levels
Calibrator Levels for AMM only	Calibrator Level 3 – 1405 µg/dL [825 µmol/L]	Calibrator Level 3 – 1050 µmol/L

11. Standard/Guidance Document Reference:

- CLSI, EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline; 2009.

12. Performance Characteristics

Calibrator

- For opened products, once the cap is removed, assigned values are stable for 7 days stored on the Dimension® clinical chemistry system.
- Once cap is removed, assigned values are stable for 30 days when recapped immediately after use and stored at 2-8°C.

The shelf life of the Dimension® CHEM III CAL is 12 months.

13. Conclusion: The Dimension® Chemistry III Calibrator (CHEM III CAL) is substantially equivalent in principle and performance to the Dimension Vista® Chemistry 3 Calibrator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 15, 2013

Siemens Healthcare Diagnostics, Inc.
c/o Rose T. Marinelli
500 GBC Drive
P.O. Box 6101/MS 514
Newark, DE 19714-6101

Re: k123321
Trade/Device Name: Dimension Chemistry III Calibrator (CHEM III CAL)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIX
Dated: February 01, 2013
Received: February 07, 2013

Dear Ms. Marinelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123321

Device Name: **Dimension® Chemistry III Calibrator (CHEM III CAL)**

Indications for Use:

The CHEM III CAL is an *in vitro* diagnostic product for the calibration of Ammonia (AMM), Carbon Dioxide (C02) and Ethyl Alcohol (ETOH) methods on the Dimension® clinical chemistry system.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.02.15 10:17:42 -05'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123321